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| 09/781,046      | 02/08/2001  | Kangsheng Wang       | 258-193             | 9275             |

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EXAMINER

TON, THAIAN N

| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 02/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/781,046

Examiner

Thai-An N. Ton

Applicant(s)

WANG, KANGSHENG

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. (See 37 CFR 1.734(b).)

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicants' Amendment, filed 12/05/02, Paper No. 9, has been entered. Claims 22-26 have been amended.

Claims 1-26 are pending. Claims 22-26 are under current examination.

#### *Election/Restrictions*

Claims 1-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group(s), there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Applicant's election without traverse of Group IV [Claims 22-26] in Paper No. 6 is acknowledged.

#### *Double Patenting*

The Terminal Disclaimer filed by Applicant on 12/5/02 has been received.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' Written Assurance pursuant to 37 C.F.R. §1.809, attachment to the Response filed 12/5/02, Paper No. 10, from the Inventor has been considered.

However, the Written Assurance Statement is unclear because there is no specific recitation of the deposit of the linker antibody, mAbC. The statement merely states that "an acceptable deposit" will be made. Furthermore, it is noted that the Written Assurance statement states that the deposit will be maintained in a public depository. Applicant is reminded that MPEP §1.809(d) states:

For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

Claims 22-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the antibody linker mAbC which is characterized by having binding affinity to sperm cells from a plurality of species of animals, wherein a sperm cell bound with the antibody linker mAbC retains the ability to fertilize an oocyte, does not reasonably provide enablement for any antibody, for the breadth claimed, characterized by having binding affinity to a sperm cell, wherein a sperm cell bound with the antibody retains the ability to fertilize an oocyte for reasons of record advanced on pages 6-8 of the prior Office action, mailed 8/22/02, Paper No. 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is directed to an antibody characterized by having binding affinity to a sperm cell, wherein a sperm cell bound with the antibody retains the ability to fertilize an oocyte. In further embodiments, the sperm cell is a human sperm, mouse sperm, cow sperm, pig sperm, chicken sperm, sheep sperm, and goat sperm, and the antibody also exhibits binding properties to a polynucleotide such that upon fertilization, the polynucleotide is introduced into the oocyte.

Applicants argue that the claimed invention is directed to an antibody that is characterized by having binding affinity to a sperm cell, and wherein the sperm cell bound with the antibody retains the ability to fertilize an oocytes. Applicants argue that the antibodies listed in the Office action, once bound to a sperm cell, inhibit the sperm cell to fertilize an oocytes, and that it follows that the antibodies do not fall into the scope of the claimed invention. See p. 5, ¶4 of the Response.

Applicants further argue that, "the fact that a few sperm antibodies in the art inhibit a sperm cell to fertilize does not mean the lack of an antibody that allows the sperm cell bound with the antibody to retain the ability to fertilize an oocytes. Quite the contrary. Applicant has obtained an antibody, mAbC, that permits a sperm cell bound with mAbC to fertilize an oocytes." See p.6, 1<sup>st</sup> ¶ of the Response.

Applicants argue that the fact that a few sperm binding antibodies in the art inhibit a sperm cell to fertilize does not mean that the need of undue experimentation to expect or obtain the claimed antibody that would allow the

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sperm cell to fertilize an oocyte. Applicants argue that the standards of "undue experimentation" have long been established and it has been ruled that, "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention" when "there was considerable direction and guidance" in the specification "all the methods needed to practice the claimed were well known." See p. 6, 2<sup>nd</sup> ¶.

Applicants' arguments have been carefully considered, however, they are not found persuasive. It is reiterated that the level of predictability and the state of the prior art of antibodies directed to sperm is such that one of skill in the art would expect such antibodies to inhibit fertilization, not allow the sperm to retain the ability to fertilize an oocyte, as claimed by the instant invention. The Examiner has provided evidence of the state of the art in the prior Office action [see Yan *et al.*, Nakamura *et al.*, Naz *et al.*, Kim *et al.*, all cited in the prior Office action] that collectively show that antibodies bound to the surface of sperm cells cause the inhibition of fertilization. Indeed, this is supported by Nakamura *et al.*, who teach that, "It is believed that antisperm antibodies cause infertility in some male and female patients." [See p. 1503, 1<sup>st</sup> paragraph]. It is maintained that the state of the art supports that, in general, antibodies directed to sperm would be expected to inhibit fertilization, contrary to "a few", as asserted by Applicant. It is maintained that although the specification provides guidance for the production of an antibody, mAbC, which retains the ability to fertilize an oocyte, when taken with the state of

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the art, which is replete with examples of how antibodies directed to sperm cause the inhibition of fertilization, it would have required undue experimentation for one skilled in the art to expect that the sperm-specific antibodies of the instant invention would retain the ability to fertilize an oocyte.

*Claim Rejections - 35 USC § 112*

The prior rejection of claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, is *withdrawn* in view of Applicants' amendment(s) to the claims.

*Conclusion*

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT  
Thái-An N. Ton  
Patent Examiner  
Group 1632

*Deborah Crouch*

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